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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,000

02/21/2007

Yuriko Taniguchi

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09/24/2009

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

NOTIFICATION DATE

DELIVERY MODE

09/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/580,000	Applicant(s) TANIGUCHI ET AL.	
	Examiner HOPE A. ROBINSON	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/06, 9/22/08, 11/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Claims 1-16 are pending. Claims 1-4 and 9-13 are under examination. Claims 5-8 and 14-16 are withdrawn from further consideration for the reasons set forth below.
2. The Preliminary Amendment filed on June 14, 2006 has been received and entered.

Priority

3. It is noted that a certified copy of the foreign document 2003-38991 filed November 19, 2003 is provided in the instant application, however, no certified English Translation of said document is in the application. In order to perfect benefit to the foreign priority document a certified translation should be provided.

Specification

4. The specification is objected to because of the following informalities:
The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic

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terminology. The use of the trademarks such as TRIXTON-X-100®, for example, has been noted in this application (see page 18). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

The specification is objected to because the priority information is missing from page 1 of the specification.

Correction is required.

Drawing

5. The drawing filed on May 19, 2006 has been accepted by the examiner.

Claim Objection

6. Claims 1-16 are objected to because of the following informalities:

Claims 1-2 and 10-11 are objected to because of a grammatical error, see for example the phrase, "characterized by comprising".

Claims 3, 9 and 12 are objected to because the article "a" is missing in front of the word "glycated".

Claim 4 is objected to because the plural form of "claim" is needed, for example, "a method according to claims 2 or 3".

Claims 5-8 and 14-16 are objected to under 37 CFR 1.75(c) as being in improper form because of multiple dependent claims 4 and 13. See MPEP § 608.01(n).

Accordingly, the claims 5-8 and 14-16 have not been further treated on the merits.

Correction is required.

Information Disclosure Statement

7. The Information Disclosure Statements filed on August 16, 2006, September 22, 2008 and November 8, 2006 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action. Note that several references have been lined through on the 8/16/06 IDS because they represent improper citations of foreign references (i.e. the country section on the form should only list for example "JP" and the "Translation section" can list information such as "English Abstract only". The references although not in proper format have been considered. Applicant is urged to resubmit the 1449 in the proper format for signature, so that the references can appear on the face of the patent once allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-4 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 1-4 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claims do not set forth how the “effect of a fructosyl lysine is reduced”. Claim 1 for example, recites “causing an enzyme” and it is unclear how or what enzyme is used to “reduce the effect of a fructosyl lysine” or what effect of a fructosyl lysine is being reduced.

Claims 1-4 and 9-13 are confusing. The claims as written, are directed to a method of reducing the effect of a fructosyl lysine compound in an assay, however, based on the open-ended nature of the claims it is unclear if the method objective is achieved, for example, claim 1 ends with “measuring the resultant product” and it is unclear what “resultant product” is measured, and what is being measured, is a property of the fructosyl lysine compound measured or a property of the enzyme used in the assay, measured.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by

Watanabe et al. (Agri. Biol. Chem. Vol. 54, No. 4, pages 1063-1064, 1990).

Watanabe et al. disclose that an enzyme was found that catalyzes deglycation of fructosyl-amino acids. The enzyme is disclosed as decomposing Amadori compounds of α -L-amino acids to the corresponding ketoaldehyde and α -L-amino acids. Watanabe et al. teach a pH of 5 to 7 (see page 1063 of the reference). Therefore, the limitations of the claims are met by the reference.

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652

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